JUL 18 2002

K021809

510(k) Summary
for
V-2100G Advanced Infant Incubator

1. SPONSOR

Atom Medical Corporation
3-18-15, Hongo
Bunkyo-Ku
Tokyo, 113-0033
Japan

Contact Person: Hiroshi Tanaka, Manager, Quality Regulatory Department
Telephone: 03-3815-2311

Date Prepared: May 31, 2002

2. DEVICE NAME

Proprietary Name: V-2100G Advanced Infant Incubator
Common/Usual Name: Infant Incubator
Classification Name: Neonatal Incubator

3. PREDICATE DEVICES

The V-2100G Advanced Infant Incubator is substantially equivalent to the following devices:

- Air Shields Isolette® Infant Incubators and Accessories
- Ohmeda Ohio Care Plus Infant Incubators and Accessories

4. INTENDED USE

The V-2100G Advanced Infant Incubator is a hooded container that is intended to provide a controlled thermal environment and isolation from ambient air for premature and neonatal infants. The V-2100G is not intended for the transport of infants.

5. DEVICE DESCRIPTION

The V-2100G Infant Incubator provides standard functions to control the incubator temperature, either by manual (air) or servo (baby) control, and air humidity. The incubator also provides an external communication function that allows data to be exported to the user's PC for evaluation and storage. In addition, the incubator provides the following optional functions: oxygen controller, pulse oximeter, and weight monitor.

The temperature in the incubator can be controlled using one of two modes: manual control mode or servo control mode. In manual control mode, the incubator air temperature is controlled to maintain the desired infant temperature. The air temperature is initially set based on the user's training and experience and is then adjusted based on the infant's needs and clinical status. In the servo control mode, a skin temperature probe is attached to the infant and is monitored by the incubator controller. The heater output is controlled to maintain the infant's skin temperature at a set value. Changes to the heater output are made gradually, so as to minimize temperature overshoot and infant stress.

6. SUBSTANTIAL EQUIVALENCE

Atom Medical Corporation makes the claim of substantial equivalence based on intended use, design, operational and technological characteristics, and principles of operation. Atom Medical Corporation believes that the descriptive information, performance test summaries, and certificates of compliance provided in this premarket notification are precise enough to demonstrate the substantial equivalence of the V-2100G Infant Incubator to the identified predicate devices. The V-2100G and the predicate devices are all intended to provide a controlled environment for neonates. The V-2100G and the predicate devices all operate in both manual and servo modes for temperature control. All devices also offer humidity control as a standard function and a variety of optional functions including oxygen supply and control, a weight monitor, and an RS-232 communications module. All devices have similar displays, alarms, and user controls.

7. PERFORMANCE TESTING

Performance testing for the V-2100G Infant Incubator has been conducted for functional and design verification. This testing demonstrates that the V-2100G Infant Incubator is in compliance with the following recognized consensus standards:

IEC 60601-1 (1988-12) Medical Electrical Equipment, Part 1: General Requirements for Safety, Amendment 1 (1991-11), Amendment 2 (1995-03)

- EN 60601-1-2 (1993) Medical Electrical Equipment, Part 1: General Requirements for Safety, Electromagnetic Compatibility-Requirements and Tests
- IEC 60601-2-19 (1990-12) Medical Electrical Equipment, Part 2: Particular Requirements for Safety o f Baby Incubators, Amendment 1 (1996-10)
- ISO 7767 (1997) Oxygen Monitors for Monitoring Patient Breathing Mixtures – Safety Requirements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

Atom Medical Corporation
C/O Ms. Sheila Hemeon-Heyer, Esq.
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K021809
Trade/Device Name: V-2100G Advanced Infant Incubator
Regulation Number: 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: May 31, 2002
Received: June 03, 2002

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021802

Device Name: V-2100G Advanced Infant Incubator

Indications For Use:

The V-2100G Advanced Infant Incubator is a hooded container that is intended to provide a controlled thermal environment and isolation from ambient air for premature and neonatal infants. The V-2100G is not intended for the transport of infants.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cusenide

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021809

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)